

REMARKS

Claims 145 to 152 and 154 to 165 are pending and under examination. Applicants have canceled claim 153 without prejudice. Applicants reserve the right to pursue all canceled subject matter in one or more continuing applications. Claims 145 and 152 have been amended to recite that the claimed polypeptides inhibit protein-protein interaction between calcineurin and NFAT. Claim 152 has been amended to be independent. Support for the amendments can be found throughout the specification, e.g., at page 3, lines 10 to 13; page 17, lines 8 to 11; page 19 lines 17 to 22, and originally filed claim 153.

Allowable subject matter and objections

Applicants acknowledge the Office's finding that claim 154 is allowable. Applicants also acknowledge the Office's finding that claims 153 and 155 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants respectfully point out that claim 155 depends directly from claim 154, which was found allowable by the Office. Accordingly, applicants request that the objection to claim 155 be withdrawn and that this claim be found allowable as well. Further, applicants have canceled claim 153 and have amended claim 152 to be independent and to incorporate the subject matter recited in claim 153. Applicants respectfully request that claim 152 be allowed.

Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 145 to 152 and 156 to 165 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. The Office alleges that insufficient guidance is provided as to the function of the claimed polypeptides¹ and that undue experimentation would be required to make and use the full scope of the claimed polypeptides. Although applicants respectfully disagree with the rejection, in order to expedite prosecution, applicants have amended claims 145 and 152 to recite that the claimed polypeptides inhibit protein-protein

¹ The Office Action paper refers at several points to "polynucleotides" and "variant polypeptides." To provide a clear record, applicants submit that the current claims do not recite the words "polynucleotides" or "variant polypeptides," and respectfully request clarification by the Office.

interaction between calcineurin and NFAT. Applicants respectfully traverse the rejection as to the claims presented herein.

As amended, claims 145-152 and 165 recite polypeptides that inhibit protein-protein interactions between calcineurin and NFAT. Skilled practitioners will appreciate that such a function is readily testable, and the specification provides ample guidance for doing so. See, e.g., page 12, line 20 to page 21, line 8; page 50, line 12 to page 52, line 15; and page 53 line 25 to page 56, line 7. Furthermore, claim 152 has been amended to recite, in independent form, all of the limitations in claim 153 (now canceled). Applicants submit that the specification is enabled for the full scope of the amended claims.

Applicants respectfully traverse the rejection of claims 156-164 because these claims depend from claim 154, which the present Office Action notes is in condition for allowance (page 8 of the Office Action paper). Claims 156-164 incorporate all of the limitations recited in claim 154. Since the Office has indicated that the specification is enabling for the full scope of claim 154 (by finding claim 154 allowable), applicants respectfully submit that the specification is also enabling for claims 156 to 164.

Further, applicants submit that the specification provides examples and guidance sufficient to enable skilled practitioners to make and use the polypeptides recited in claims 156 to 164 without undue experimentation. For example, the specification discloses, starting at page 52, line 16, that NFAT or biologically active fragment thereof can be fused to another peptide or protein, such as maltose-binding protein, glutathione S-transferase, green fluorescent protein and/or a peptide tag. The specification also provides several examples where fusion proteins were made and used (see, e.g., Examples 2, 6, and 12). Applicants submit that with such detailed information, a skilled practitioner would know how to make and use all fusion proteins included within the scope of claims 156 to 164 through routine and predictable experimentation.

Applicants submit that the Office's concerns regarding enablement are unwarranted in view of the functional limitations in certain of the claims and in view of the detailed information provided in the specification. Thus, applicants request that the present rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 145-152 and 156-165 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to satisfy the written description requirement.

Applicants respectfully traverse this rejection because they satisfy the written description requirement for the full genus of claimed polypeptides through a description of a representative number of species, as well as by disclosure of relevant, identifying characteristics of the polypeptides, i.e., the minimum sequence they must contain (e.g., SEQ ID NO:77) and their ability to inhibit protein-protein interactions between NFAT and calcineurin (*see* the MPEP at §2163(II)(A)(3)(a)(ii)). According to the MPEP §2163 (II)(A)(3)(a)(ii):

A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus.

Applicants submit that the polypeptides described in the specification (e.g., by providing amino acid sequences) are representative of the entire genus of polypeptides, and that a sufficient variety of species is described to reflect the variation within the genus. The claimed polypeptides include fragments (of differing lengths) of the conserved regulatory domain of Nuclear Factor of Activated T-cell (NFAT). The conserved regulatory domain is described in the specification by reference to art-known NFAT sequences. See, e.g., page 17, line 23 to page 18, line 8; and page 18, line 23 to page 19, line 13. Further, applicants have described not one, but dozens of examples of the claimed polypeptides with differing lengths. See, e.g., SEQ ID NOs: 5 to 77. Moreover, the recited sequences are described in the specification as being related to a functional characteristic of the claimed polypeptides, i.e., their ability to inhibit protein-protein interactions between NFAT and calcineurin. In fact, the recited amino acid sequences (described in the sequence listings and the specification) are themselves distinguishing structural features or attributes shared by all the members of the claimed genus. Thus, applicants submit that the claims comply with the written description requirement because the specification

describes a number of polypeptides which, as a group, are representative of the entire genus of polypeptides and reflect the variations that may occur within this genus. Accordingly, applicants request that the present rejection be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 102

Claims 145, 146, 152, 156, 165 stand rejected under 35 U. S. C. § 102(b)² as allegedly anticipated by SEQ ID NO:4 (see Sequence Comparison A provided by the Office) in U.S. Patent No. 5,612,455 (the '455 patent). Applicants respectfully traverse the rejection because the cited patent does not appear to disclose each and every limitation recited in the current claims.

Claims 145, 146, 152 (prior to amendment) and 165 recite polypeptides that comprise no more than 150 amino acids of the NFAT conserved regulatory domain. On the other hand, Sequence Comparison A indicates that the '455 patent's SEQ ID NO:4 includes 716 amino acids of the human NFATc protein. The cited sequence appears to contain a complete NFAT conserved regulatory domain, which is approximately 300 amino acids in length.³ Thus, the cited sequence appears to contain more than 150 amino acids of NFAT conserved regulatory domain and, therefore, does not anticipate claims 145, 146, 152, and 165.

Claim 156 recites a fusion protein that comprises the isolated polypeptide consisting of any one of SEQ ID NO: 5, 6, 7 or 71 fused to a second protein "other than an NFAT protein." The '455 patent does not appear to disclose a polypeptide that includes (i) the amino acid sequence of SEQ ID NOs: 5, 6, 7 or 71 fused to (ii) a non-NFAT protein sequence.

In order to be anticipating, the cited reference must disclose each and every limitation recited in the claims. The '455 patent does not appear to do so. Accordingly, for the reasons

² The present application is a continuation of U.S. Patent Application Serial No. 09/248,620, filed February 11, 1999, which claims the benefit of priority from U.S. Provisional Application Serial No. 60/074,467, filed February 12, 1998. The issue date of the '455 patent is March 19, 1997, which is less than one year from applicants' effective filing date. Accordingly, the '455 patent does not appear to be a §102(b) reference. Applicants submit that the claims are not anticipated by the '455 patent for the reasons discussed above. However, applicants also reserve the right to attempt to swear back of this reference, e.g., via a declaration under 37 CFR 1.131, at a later time.

³ Applicants refer the Examiner to page 18, line 23 to page 19 line 4 of the current specification, teaching that the conserved regulatory domain in various known NFAT proteins is approximately 300 amino acids in length.

presented above, applicants respectfully request that the rejection be reconsidered and withdrawn.

Claims 145-151 stand rejected under 35 U. S. C. § 102(b) as allegedly anticipated by WO 96126959 (the '959 application) (see Sequence Comparison B provided by the Office). Applicants respectfully traverse this rejection.

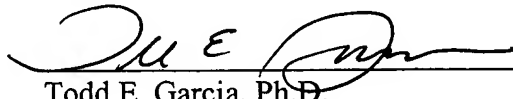
Claims 145-151 recite polypeptides that comprise no more than 150 amino acids of the NFAT conserved regulatory domain. On the other hand, Sequence Comparison B indicates that the cited sequence of the '959 application is 902 amino acids in length. The cited sequence appears to contain a complete NFAT conserved regulatory domain. Thus, like the '455 patent, the '959 application does not appear to disclose each and every limitation recited in the pending claims. Accordingly, applicants submit that the '959 application does not anticipate claims 145 to 151 and respectfully request that the rejection be reconsidered and withdrawn.

CONCLUSION

Applicants respectfully request that all pending claims be allowed. A Petition for 3-Month Extension of Time for response, along with a check for \$510, is enclosed. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 10861-004002.

Respectfully submitted,

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